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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,803	02/09/2004	Ralph A. Heasley	XANO-42	9066

26875 7590 05/10/2007
WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
05/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,803	HEASLEY, RALPH A.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64 and 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Restriction/Election

Applicant's election of group V claims 64-65 in the reply filed on 3/16/2007 is acknowledged. The restriction election has been made without traverse. Claims 1-63 and 66-93 are withdrawn from consideration. The restriction requirement elected is made final. Claims 64-65 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hallwood (U.S. 6,159, 965) in view of Garret et al. (U.S 4,985,419) and further in view of Adam et al. (Acta Pharmaceutica Hungarica, 60, 1990, 197-204).

Hallwood teaches a pharmaceutical formulation of methotrimeprazine (levomepromazine), a phenothiazine as an anti-emetic composition (see Abstract) for parenteral administration.

The reference does not teach terminally sterilized formulation of levomepromazine.

Garret et al. teaches pharmaceutical composition of phenothiazine derivatives for parenteral administration. The reference teaches that sterile compositions for parenteral administration can be in the form of perfusions, solutions, suspensions or emulsions and sterilization may be carried out in several ways such as aseptic filtration, by incorporating sterilizing agents in the composition, by irradiation or by heating and also be in the form of solid which can be dissolved at the time of use in a sterile injectable medium (col. 110, lines 33-48).

It would have been obvious to one of ordinary skill in the art at the time of the invention to sterilize a pharmaceutical formulation of levomepromazine, a phenothiazine because Garret teaches sterile compositions of phenothiazine derivatives for parenteral administration. One of ordinary skill in the art at the time of the invention would have been motivated to sterilize levomepromazine (pheonthiazine) is to use the drug for parenteral administration, for stability of the drug, for public's safety, and for producing quality drugs.

Hallwood and Garret does not teach a concentration of the impurity of levomepromazine in the formulation.

Adam et al. teaches chromatographic purity test of levomepromazine with 0.38 % impurity (p 202, lines 14-15) and teaches the quantities of intermediate impurities in the range of 0.15-0.96% (See Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a formulation of levomepromazine with a concentration of total impurities of less than about 3% by weight per volume because Adam teaches

levomepromazine with less than 3% by weight per volume impurity and one of ordinary skill in the art would have been motivated to have less or no impurity in the formulation for the safety, efficacy and therapeutic benefits of the drug, levomepromazine that will be administered to a patient as an anti-emetic.

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hallwood (U.S. 6,159, 965), in view of Garret et al. (U.S 4,985,419), in view of Adam et al. (Acta Pharmaceutica Hungarica, 60, 1990, 197-204) as applied to claim 64 and further in view of Vargas et al. (Pharmazie, 2003, May 58(5): 315-9).

Hallwoood, Garrett et al. and Adam et al. teachings discussed as above.

The references do not teach the impurity as levomepromazine sulfoxide.

Vargas et al. teaches that levomepromazine is photolabile under UV-A and UV-B light in aerobic conditions and irradiation of a methanol solution of the drug produces one photoproduct to sulfoxide (See Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to expect in the formulation of levomepromazine, levomepromazine sulfoxide as an impurity because Vargas et al. teaches that levomepromzine when subjected to light is oxidized to sulphoxide compound. It would have been obvious to one of ordinary skill in the art at the time of the invention that levomepromazine sulfoxide impurity is less than about 2% because Adam et al. teaches levomepromazine with 0.38 % impurity.

Conclusion

Translation of the prior art Adam et al. (Acta Pharmaceutica Hungarica, 60, 1990, 197-204) has been requested.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER